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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,205	02/09/2001	Stanislaus Laurens Johan Wouters	4753US	7934

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EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/780,205	WOUTERS ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10/08/04 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: ~~_____~~.

   Claim(s) objected to: ~~_____~~.

   Claim(s) rejected: *2,9,10,13-22,24,27-31,35 40,and 42-49*.

   Claim(s) withdrawn from consideration: *23,25 and 26*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because:

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2, 9, 10, 13-22, 24, 27-31, 35 and 40, 42- 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody or fragment thereof and composition comprising said antibody or fragments which binds to an epitope and broken from an epitope under specifically chosen conditions recited in Table 1 that binds to a dye and detects the plaque and suitable for detection of dental plaque or other oral pathogens does not reasonably provide enablement for an antibody or fragment thereof which binds to en epitope and broken from an epitope under broadly recited conditions that is capable of use in any therapeutic or any cosmetic treatment of externally accessible parts of the human or the animal body for the same reasons set forth in the previous Office Action, mailed 08/10/04.

Applicant's arguments, filed 10/08/04 have been fully considered, but have not been found convincing.

Applicant asserts that: independen claim 40 is amended to recite conditions of C and D.

Contrary to Applicant's assertion, it is noted that conditions C, requires that antibody binds to epitope at specific pH of 8.5 and 1M NaCl , and is broken at pH of 7.0 and conditions D, requires that antibody binds to epitope at specific pH of 8.5, and is broken at pH of 4.5 + 1 M NaCl (see Table 1) The amended claim 40 does not recited said condition .

In addition, in the previous Office Action, mailed on 08/10/04 the issue was about benefits of the antibody or fragments thereof that are capable of binding to and broken from an epitope under specifically chosen condition would be other than being suitable for targeting and local administration of active substances for therapeutic treatment of infections in the oral cavity. As was stated in the previous Office Action, Applicant himself acknowledge that the ability of an antibodies to be broken from an epitope at any desired moment can be of benefit only for removing the dye which are used for the detection of dental plaque or other oral pathogens, without lips, tongue and gums remained coloured for a long time (Page 2, lines 19-34 of the specification as filed). The specification as filed does not adequately teach what other benefits of the antibody or fragments thereof that are capable of binding to therapeutically or cosmetically or diagnostically active substance and able to bind to and broken from an epitope u under specifically chosen condition would be.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 9, 10, 13-22, 28, 30-31, 35, 40, and 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beggs et al., (US Patent NO: 5,490,988) in view of Goding (Monoclonal Antibodies; Principles and Practice, 1983, Academic. Press, New York. see entire book, particularly pages 44-45) for the same reasons set forth in the previous Office Action, mailed 08/10/04.

Applicant's arguments filed on 10/08/04 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) Since the Goding reference dose not refer to the antibodies of Beggs et al., the cited references do not established that the antibodies of Beggs et al necessary disassociate at pH of 7.0. Thus the theory of inherency cannot be used to establish that the cited references teach or suggest each and every element of amended claim 40.

Contrary to Applicant's assertion it is noted that the rejection is under 35 USC103, not under 35 USC 102.

In response to applicant's arguments that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine 5 USPQ2d 1596 (Fed. Cir 1988) and In re Jones 21 USPQ2d 1941 (Fed. Cir. 1992). In this case Beggs et al, teach an antibody and antibody fragment, comprising F (ab) or Fv fragments that are able to bind to a target site through antibody -antigen binding at conditions lie within physiologically acceptable limits (see entire document , column 1, lines 39-41 and column 2, lines 18-20 in particular). pH of between 6 and 8 would be considered by one of ordinary skill in the art to lie within physiological limits. Beggs et al., further teach that antibody or antibody fragment is capable of use in a target or temporally diagnostic of externally accessible parts of a human body, particularly bind to an antigenic component of dental plaque under physiologically acceptable limits (see column 4, lines 16-30 in particular). Beggs et al., also 2teach that the antibody or fragment thereof binds therapeutic active

agent, wherein therapeutic agent comprises an enzyme (see column 5, lines 19-42. in particular). The antibody fragment is a fragment of an antibody to Streptococcus. mutans and the therapeutic agent is glucose oxidase (column 4, lines 22-27 in particularly). Begges et al., also teach that the antibody or fragment thereof will be used to detect plaque in oral cavity or capable of bleaching teeth (column 4, lines 25-60 in particular). Beggs et al., also teach that antibody and the therapeutic agents are incorporated in one or more pharmaceutically acceptable dilutent or carrier (column 5, lines 44-46 in particular). Beggs et al., also teach composition useful as a teeth cleaning agent, mouthwash, toothpaste comprising antibody or fragment thereof (column 5, lines 65-67 and column 6, lines 1-6 in particular).

Goding teaches that during optimization of each purification protocol for each antibody of interest and a fragment thereof, the parameters such as pH and ionic strength play an essential role and that it is an inherent properties of all antibody and fragment to bind to an epitope under one set of specifically chosen conditions and be eluted from an epitope (bound of antibody to an epitope is broken) under specifically chosen different conditions. (pages 44-45 in particularly).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine all operable and optimal rangers of pH and ion strength at which antibody or fragment thereof binds to and eluted from an epitope, as taught by Goding and use it for antibody or fragment thereof taught by Beggs et al. Thus, contrary to Applicant' s assertion it is the Examiner position that independent claim 40 and dependent claims 2, 9, 10, 13-22,24, 27-30 35, 43 and 44 are obvious over the prior art of Beggs et al., and Goding. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144.

4. Claims 2, 9, 10, 13-21, 24, 27, 28, 30, 31, 35, 40 and 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummins et al.,(EP 0736544) in view of Goding (Monoclonal Antibodies; Principles and Practice, 1983, Academic. Press, New York. see entire book, particularly pages 44-45 for the same reasons set forth in the previous Office Action, mailed 08/10/04.

Applicant's arguments filed on 10/08/04 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) Cummins et al. does not alone or in combination with Goding teach or suggest binding and dissociation of the monoclonal antibodies as recited in the amended claim 40; (2) there is no suggestion or motivation to combine the cited references; (v) Contrary to Applicant's assertion it is the Examiner position that Cummins et al. teach an monoclonal antibody and fragment thereof to salivary peliicle, which are capable of recognizing cryptitopes . These antibody and fragment thereof are particularly suitable to treat oral cavity (see entire document, Abstract in particular). Cummins et al. teach various binding conditions that lie within physiologically acceptable limits, including pH and ion strength (page 4, lines 38-40 in particular). pH of between 6 and 8 would be considered by one of ordinary skill in the art to lie within physiological limits. Cummins et al. also teach that antibody and fragment thereof binds diagnostically, therapeutically or cosmetically active substance (see Abstract and pages 3-4 in particular) and can be visualized by using fluorescent labeled antibodies (page 11 in particular). Cummins et al., teach a composition comprising at least one antibody and physiologically acceptable dilutent that is useful as a cleaning agent (see Example 5 in particular) Cummins et al., teach that diagnostically, therapeutically or cosmetically active substance comprises enzyme such as a proteases, including papain, pepsin, trypsin, ficin and bromelin (page 3, lines 35-55 in particular). Cummins et al. teach the antibody or fragment thereof is capable of binding an epitope of a pathogenic micro-organism (page 3, lines 1-5 in particular) and can be used for teeth bleaching (page 3, lines 3-5 in particular).

Goding teaches that during optimization of each purification protocol for each antibody of interest and a fragment thereof, the parameters such as pH and ionic strength play an essential role and that it is an inherent properties of all antibody and fragment to bind to an epitope under one set of specifically chosen conditions and be eluted from an epitope (bound of antibody to an epitope is broken) under specifically chosen different conditions. (pages 44-45 in particularly).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine all operable and optimal rangers of pH and ion strength at which antibody or fragment thereof binds to and eluted from an epitope, as taught by Goding and use it for antibody or fragment thereof taught by , Cummins et al. Thus, contrary to Applicant' s assertion it is the Examiner position that independent claim 40 and dependent claims 2,9,10, 13-22, 24, 27-30 35, 43 and 44 are obvious over the prior art of Cummins et al. and Goding. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144

5. Claim 29 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Beggs et al., (US Patent NO: 5,490,988) in view of Goding (Monoclonal Antibodies; Principles and Practice, 1983, Academic. Press, New York. see entire book, particularly pages 44-45) as applied to claims 2, 9, 10, 13-22, 28, 30-31, 35, 40, and 42-49 as above, and further in view of Cole et al., (Immunol. &Infect. Diseases 1993, 3, 33-35) for the same reasons set forth in the previous Office Action, mailed 08/10/04

Applicant's arguments, filed 10/08/04 have been fully considered, but have not been found convincing.

Applicant asserts that claim 29 is non-obvious at the very least as indirectly depending from non-obvious independent claim 40.

Contrary to Applicant's assertion , as has been discussed , supra it is the Examiner position that independent Claim 40 is unpatentable over Beggs et al ., in view of Goding.

The teachings of Beggs et al., and Goding have been discussed, supra.

The claimed invention differs from the reference teaching only by the recitation of an antibody capable of binding Porphyromonas gingivalis.

Cole et al., teach an antibody to Porphyromonas gingivalis (see entire document, Abstract in particular) . Cole et al., further teach that this antibody play essential role in the immunopathology of periodontal disease.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of Cole et al., and those of Beggs et al., and substitute antibody capable of binding to one pathogenic micro-organism associated with periodontal disease with antibody capable of binding with another pathogenic micro-organism associated with periodontal disease.

One of ordinary skill in the art at the time the invention was made would have been motivated do so, because antibody to Porphyromonas gingivalis are essential in the immunopathology of periodontal disease and could be used to delivery of the therapeutic agents to the target site as taught by Beggs et al.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claim 43 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Beggs et al., (US Patent NO: 5,490,988) in view of Goding (Monoclonal Antibodies; Principles and Practice, 1983, Academic. Press, New York. see entire book, particularly pages 44-45) as applied to claims 2, 9,10, 13-22, 28, 30-31, 35, 40, and 42-49 as above, and further in view of Fischer (US Patent 5,571,511) mailed 08/10/04

Applicant's arguments, filed 10/08/04 have been fully considered, but have not been found convincing.

The teachings of Beggs et al., and Goding have been discussed, supra.

The claimed invention differs from the reference teaching only by the recitation of an antibody capable of binding Staphylovovvus epidermidis.

US Patent '511 teach an antibody to Staphylococcus epidermidis (see entire document, Abstract in particular) . US Patent '511 further teach that this antibody play essential role in the new therapy for treatment of Staphylococcus infection (see column 4, lines 31-35 in particular

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '511 and those of Beggs et al., and substitute antibody capable of binding to one pathogenic micro-organism associated with periodontal disease with antibody capable of binding with another pathogenic micro-organism associated with periodontal disease.

One of ordinary skill in the art at the time the invention was made would have been motivated do so, because antibody to Staphylococcus epidermidis play essential role in the new therapy for treatment of Staphylococcus infection and could be used to delivery of the therapeutic agents to the target site as taught by Beggs et al.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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